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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
ANGELL, JON E

ART UNIT	PAPER NUMBER
1635	12

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,088	HERZOG, HERBERT	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *4,6 and 15-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 7-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-25 are pending in the application.

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-14) and of the species SEQ ID No. 4 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the claims have been amended to remove "functionally equivalent" language, and the claims are linked by a common structural feature (SEQ ID No. 1). This is not found persuasive because the lack of unity was determined based on the claims encompassing "functionally equivalent" molecules, and functionally equivalent molecules were known in the art; therefore no special technical feature existed to link the claims. The applicant argues that the "functionally equivalent" language has been removed from the claims, and the claims should be rejoined. It is pointed out that claim 11 was not amended and still encompasses "functionally equivalent" molecules. Furthermore, the determination of unity of invention is made based on the claims as written at the time the claims are originally examined. Amendment of the claims after a determination that the inventions lack a linking special technical feature is insufficient. There is no special technical feature linking the inventions; therefore, restriction is appropriate.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Furthermore, claims 4 and 6 are withdrawn from further consideration as being drawn to non-elected species.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-3, 5 and 7- 14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The instant claims are drawn to a polynucleotide encoding an NPY-Y7 receptor and a host cell comprising said polynucleotide.

Credible Utility

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the claimed invention. The only cited utilities identified by the examiner are to produce polypeptide, which can be used to identify agonists and antagonists of the polypeptides, which can then be used in therapeutic treatments, methods of detecting mutations in the nucleic acid sequence and methods of detecting altered levels of the soluble form of the receptor are cited. These utilities are credible.

Well-Established Utility

Upon identification of credible utilities, the next issue is whether there are any well-established utilities. No well established utilities for this specific NPY-Y7 nucleic acid and polypeptide are identified in either the specification or in the cited prior art.

Substantial utility

Given the absence of a well-established utility, the next issue is whether substantial utilities are disclosed in the specification. The specification discloses that the NPY family of receptors, when activated, influences a diverse range of important physiological parameters including effects on psychomotor activity, central endocrine secretion, anxiety, reproduction, vasoactive effects on the cardiovascular system, and stimulation of food consumption (p. 1, second paragraph). The specification also discloses that NPY agonists and antagonists may have commercial value, for example, as potential anti-hypertensive agents, cardiovascular drugs, neuronal growth factors, anti-psycotics, anti-obesity agents. The applicant contends that the "ability to produce the NPY receptors by recombinant DNA technology would be advantageous" (paragraph spanning page 1 and page 2).

However, there is no disclosure in the specification or in the prior art that teaches the specific function of the NPY-Y7 receptor. The only evidence that NPY-Y7 may be associated with any disorder, or that treatment targeted to the NPY-Y7 receptor is solely based on the fact that NPY-Y7 is a member of the NPY family of receptors. Without a specifically identified function of NPY-Y7, the NPY-Y7 receptor and the nucleic acid encoding it has no patentable utility.

As noted in the utility guidelines, methods of treating unspecified diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities (see page 6 of the Utility guideline training materials). If there was evidence of the association of NPY-Y7 with any disease state, this evidence might be sufficient to provide a substantial utility. First, there is NO specific function of NPY-Y7 disclosed in the specification. Second, there if NO data in the specification that NPY-Y7 is associated with any disorder. Thus, the specification does not support a substantial utility for NPY-Y7, a protein with unknown function and which is not associated with any specific disease.

Specific Utility

In the current case, even if the substantial utility argument above were found unpersuasive, NPY-Y7 (and the nucleic acid encoding it) lacks specific utility because, as noted above, no specific function of NPY-Y7 has been identified. The fact that NPY-Y7 is a member of the NPY family of receptors does not provide a specific utility because there is no direct or even indirect connection made between any particular utility and NPY-Y7. As the utility guideline training materials note on page 5-6, "Similarly, a general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed". Here, there is disclosure of a very broad range of conditions associated with other NPY receptor family members. However, there is no evidence that NPY-Y7 is associated with any of these disorders, or that it can be involved in diagnosing any specific disorder. Therefore, the NPY-Y7 (and nucleic acid encoding it) has no specific utility.

Finally, with regard to the utility analysis, the current situation directly tracks Example 4 of the utility guidelines, where a protein of entirely unknown function was characterized as lacking utility.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5 and 7- 14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial

asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The instant claims are drawn to a nucleic acid encoding an NPY-Y7 receptor polypeptide and a cell comprising said nucleic acid. Therefore, the nature of the invention is recombinant molecular biology.

The breadth of the claims

The breadth of the claims 11-14 is very broad because the claims encompass any functionally equivalent fragment of NPY-Y7. Therefore, the claims encompass thousands of different nucleic acid molecules because every nucleic acid substitution or deletion in the NPY-Y7 open reading frame is encompassed by the claims. Claims 1-3, 5 and 7-10 encompass nucleic acids encoding polypeptides that comprise a specific N-terminal amino acid sequence. NPY-Y7 is the only polypeptide known in the prior art to comprise the amino acid sequence.

However, the claims encompass any nucleic acid encoding any polypeptide comprising the 14 amino acid sequence. Therefore, these claims are broad as well.

The unpredictability of the art and the state of the prior art

The NPY-Y7 receptor was not recognized in the prior art; therefore, it is believed that NPY-Y7 was novel at the time of filing. NPY-Y7 is disclosed in the specification as a member or the NPY family of receptors (p. 1). Several NPY family members were known in the art at the time of filing (see Blomqvist et al., TINS Vol. 20, No. 7, p. 294-298; 1997). The NPY family was known to be a family of receptors that had a very broad range of function, and were associated with a very broad range of disease/disorders. The function of NPY-Y7 was not known (as it had not been identified) and there is no evidence that NPY-Y7 is associated with any disease/disorder.

Working Examples and Guidance in the Specification

The specification discloses the cDNA sequence of the human and mouse NPY-Y7 gene, and has a working example where the cDNA expresses the human NPY-Y7 receptor in COSm7 cells (see p. 7). However, there are no working examples or guidance in the specification disclosing the specific function of NPY-Y7. There is also no disclosure directly associating NPY-Y7 with any specific disease. Without a specifically disclosed function or association with a disease, further experimentation is required to determine the utility of NPY-Y7.

Quantity of Experimentation

The quantity of experimentation in this area is extremely large since the function of NPY-Y7 has not been determined. In order to determine the function of the NPY-Y7 receptor, one

would have to associate the receptor with a specific intracellular signaling pathway. This would require the identification of molecules that interact with the receptor. One would also have to determine the effects of activating the receptor, such as cell growth, gene expression, metabolism, etc. In order to associate NPY-Y7 with a disease one would have to show that altered expression of NPY-Y7 results in disease, or that expression of a mutant form of NPY-Y7 results in disease. In order to determine which diseases were associated with NPY-Y7, one would have to look for mutation of NPY-Y7 and measure the level of NPY-Y7 in every possible disease. Another way to possibly identify the function of NPY-Y7 and to possibly identify disease associated with NPY-Y7 would be to create transgenic animals that overexpress NPY-Y7 or "knock-out" animals which do not express any NPY-Y7. However, there is no assurance that the transgenic animals will display a phenotype that would help identify the function of NPY-Y7 or any disease it may be associated with.

Level of the skill in the art

The level of the skill in the art is deemed to be high.

Conclusion

Considering the breadth of the claims, lack of a specific function of NPY-Y7, the lack of guidance in the specification; and the high degree of skill required, it is concluded that the amount of experimentation required to use the claimed invention is undue.

5. Claims 3, 5 and 7-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims encompass polynucleotides that encode NPY-Y7 receptors of human origin that are **about** 408 amino acids in length (claim 3), NPY-Y7 receptors of mouse origin that are **about** 405 amino acids in length (claim 5), a polynucleotide comprises a nucleotide sequence showing at least 90% homology to nucleotides 1 to 1903 or to nucleotides 369-1592 of SEQ ID No. 4 (claim 7), a polynucleotide comprises a nucleotide sequence showing at least 95% homology to nucleotides 1 to 1903 or to nucleotides 369-1592 of SEQ ID No. 4 (claim 8), a polynucleotide comprises a nucleotide sequence substantially corresponding to that shown in nucleotides 1 to 1903 or to nucleotides 369-1592 of SEQ ID No. 4 (claim 9), and a polynucleotides molecule encoding an NPY-Y7 receptor or a functionally equivalent fragment thereof (claim 11).

Therefore, the instant claims encompass nucleic acids which are different from those disclosed in the specification, and include variants for which no written description is provided. This large genus is represented in the specification by only the named SEQ ID Nos. Thus, applicant has express possession of only SEQ ID Nos: 2-5, in a genus which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a 'representative number' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Here, no function or no common structural elements or attributes of the sequences are disclosed. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that:

> "In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, certain specific SEQ ID Nos are described, but no function of the NPY-Y7 receptors are disclosed.

Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which represent functional portions, mutations or other polymorphisms of nucleic acids encoding NPY-Y7 receptors. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

J. Eric Angell, Ph.D.
June 14, 2002